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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,078	12/21/2000	Woodrow C. Monte	32166.00002	2298

7590 10/20/2003

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	12

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/747,078	MONTE, WOODROW C.	
	Examiner	Art Unit	
	Shaojia A Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 30, 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-41* is/are pending in the application.

4a) Of the above claim(s) *10 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-9,11 and 13-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 30, 2003 has been entered in Paper No. 10.

This Office Action is a response to Applicant's request for continued examination (RCE) filed July 30, 2003 in Paper No. 10, and amendment and response to the Final Office Action (mailed January 28, 2003), filed July 30, 2003 in Paper No. 11 wherein claims 42-46 are cancelled. Currently, claims 2-41 are pending in this application.

It is noted that claims 2-41 has been last amend in Paper No. 8 filed November 12, 2002.

It is noted that claims 10 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species in Paper No. 6, submitted March 12, 2002.

Claims 2-9, 11, and 13-41 are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4-9, and 13-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record stated in the Office Action dated January 28, 2003.

The recitation, "active" in claim 2 render claims 2, 4-9, and 13-41 indefinite. Applicant's remarks filed on July 30, 2003 in Paper No. 11 with respect to this rejection have been fully considered but are not deemed persuasive for the following reasons. Applicant asserts that "an active" in claim 2 and "another substance" in claims 15 and 25, are defined in the specification at page 1, lines 11-23. As noted in MPEP 2111, during patent examination, claims are given their **broadest** reasonable interpretation. It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim. However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994).

Hence, one of ordinary skill in the art could not interpret the metes and bounds of the patent protection desired as to "active" and "another substance" encompassed thereby.

Moreover, the recitation "would" in claim 2 render claims 2, 4-9, and 13-41 indefinite, contrary to Applicant's assertion that "There is nothing indefinite about the use of "would", since the recitation "would" renders the uncertainty if the temperature denatures the active herein. According to the ordinary and customary meaning of

"would" provided by a dictionary: "wished" or "desired" for example (see the definition provided by Merriam-Webster's Collegiate Dictionary, Tenth Edition, 1998, page 1365, PTO-892), Thus, the claims herein are indefinite as to whether the active herein certainly denatures at the temperature or merely as wished or desired.

Further, the recitation of "A method for including a device....the method comprising including the device in the composition" renders the instant claims unclear as to one of ordinary skill in the art would not understand what the utility of the claimed method would be, i.e., merely including a device, and whether the device in the composition or the composition in the device.

Claim 15 recites the limitation "the beneficial effect". There is insufficient antecedent basis for this limitation in the claim since claims 2 and 11 do not recite "the beneficial effect".

Claim 33 recites the limitation "the structure". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-9, 11, 13-19, 22-26, 28, and 31-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Monte (5,707,843, of record).

Monte discloses a method therein including steps: adding (including) an enzyme or lactose-converting enzyme to a composition, heating the composition therein to a temperature to a selected temperature for a time sufficient to at least pasteurize the composition or the dairy product therein (see col.2 lines 18-22 and claim 4 step c at line 228-29, in particular) which reads on the instant denaturing temperature that denatures an active broadly, and packaging the enzyme composition, or cooling the enzyme composition. Monte also discloses the lactose enzyme composition therein is a food product such as a milk product. Moreover, Monte discloses that the lactose therein can be converted from 50% to 99% and that the composition has pH of 6.0 or less. See abstract, col.1 lines 21-39, col. 2. lines 7-10 and 18-49, col.5-6, in particular col.5 lines 36-48, and claims 4-8. The packaged product of Monte or packaging the enzyme composition of Monte reads on the instant container comprising the composition. Monte also discloses the method or process for sterilizing a dairy product (see col.1 line 63 to col.2 line 12).

Thus, the disclosure of Monte anticipates claims 2-9, 11, 13-19, 22-26, 28, and 31-41.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-22, 23, 27, 29-30 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monte (5,707,843, of record) in view of Monte (5,578.336 and 5,424,299, of record).

The same disclosure of Monte has been discussed above (see supra at page 5).

Monte does not expressly disclose providing a tablet including the active, and the tablet being coated with sugar and that the food may be an enteral food. Monte does not expressly disclose that the heating temperature is 180F or higher, and that the outer surface of the tablet is treated with gamma rays.

Monte (5,578.336) discloses that the coating of the enzyme or vitamin candy composition therein is sugar or sugarless sweetener in a form as oral ingestion of tablets. See abstract, col.1 lines 15-18, and col.2 especially lines 65-67, and Examples.

Monte (5,424,299) discloses that the food containing enzyme composition therein is an enteral food. See abstract, col.1 lines 64-66, Examples and claims 1-9.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a tablet including the active, the tablet being coated with sugar and prepare the particular food, an enteral food, and to heat the composition to 180F or higher, and to treat the tablet with gamma rays.

One having ordinary skill in the art at the time the invention was made would have been motivated to provide a tablet including the active, the tablet being coated with sugar and prepare the particular food, an enteral food, since these steps herein i.e., providing a tablet including the active, the tablet being coated with sugar and preparing

the particular food, an enteral food, are considered well within conventional skills in food science, involving merely routine skill in the art, and also taught by Monte (5,578.336 and 5,424,299) .

Moreover, the determination of how high the temperature to be raised in the heating based on the known denaturing temperature of the active given is considered well within well within conventional skills in the art, involving merely routine skill in the art since Monte (5,707,843) discloses the heating step herein. Further, using gamma rays for sterilizing a tablet is well known in the art.

Thus, the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on July 30, 2003 in Paper No. 11 with respect to this rejection made under 35 U.S.C. 103(a) in the previous Office Action have been fully considered but are not deemed persuasive. These remarks are believed to be adequately addressed by the rejections presented above.

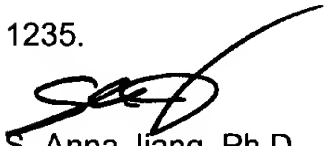
The record contains no clear and convincing evidence of nonobviousness or unexpected results for the combination method herein over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
October 7, 2003